COMMONWEALTH of VIRGINIA

DEPARTMENT OF ENVIRONMENTAL QUALITY

Valley Regional Office

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Secretary of Natural Resources

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Robert G. Burnley
Director

R. Bradley Chewning, P.E.
Valley Regional Director

STATE AIR POLLUTION CONTROL BOARD ENFORCEMENT ACTION

ORDER BY CONSENT ISSUED TO

Merck & Co., Inc.
Registration #: 80524

SECTION A: Purpose

This is a Consent Order issued under the authority of Va. Code §§ 10.1-1184, -1307(D), -1309, and -1316(C), between the State Air Pollution Control Board and Merck & Co., Inc., for the purpose of resolving certain alleged violations of environmental law and regulations.

SECTION B: Definitions

Unless the context clearly indicates otherwise, the following words and terms have the meaning assigned to them below:

1. "Va. Code" means the Code of Virginia (1950), as amended.

2. "Board" means the State Air Pollution Control Board, a permanent citizens' board of the Commonwealth of Virginia as described in Code §§ 10.1-1301 and 10.1-1184.

3. "Department" or "DEQ" means the Department of Environmental Quality, an agency of the Commonwealth of Virginia as described in Va. Code § 10.1-1183.

4. "Director" means the Director of the Department of Environmental Quality.

5. "Order" means this document, also known as a Consent Order, and incorporates the additional terms and conditions as set out in Appendices A and B to this document.

6. "Merck" means Merck & Co., Inc., a New Jersey-based pharmaceutical company authorized to conduct business in the Commonwealth of Virginia.

7. "Facility" means Merck's pharmaceutical manufacturing plant, also known as the Stonewall Plant, located at 2778 South East Side Highway, Elkton, Virginia.

8. "VRO" means the Valley Regional Office of DEQ, located at 4411 Early Road, P.O. Box 3000, Harrisonburg, Virginia 22801.

9. "CFR" means Code of Federal Regulations.

10. "Pharmaceutical MACT" means 40 CFR 63, Subpart GGG.

SECTION C: Findings of Facts and Conclusions of Law

1. Merck owns and operates a large pharmaceutical manufacturing facility known as the Stonewall Plant located in Elkton, Virginia. The Stonewall Plant manufactures a variety of pharmaceutical products that result in the emission of various hazardous air pollutants (HAPs). The Stonewall Plant has been in continuous operation since 1941.

2. Section 112 of the Clean Air Act directs the U.S. Environmental Protection Agency (EPA) to promulgate Maximum Achievable Control Technology (MACT) standards for industrial source categories in order to control emissions of hazardous air pollutants. MACT requirements apply to all "major" sources in a designated industrial source category, i.e., those sources with the potential to emit 10 tons or more per year of any single HAP or 25 tons or more per year of total HAPs. EPA proposed the MACT requirements for the pharmaceutical industry on April 2, 1997. 62 FR 15754. EPA gave all interested parties, including pharmaceutical manufacturers, the opportunity to comment on the proposed Pharmaceutical MACT.

3. The Stonewall Plant had the potential to emit 10 tons or more per year of certain individual hazardous air pollutants and 25 tons or more per year of total hazardous air pollutants, and was considered a major source of HAP emissions under Section 112 of the Clean Air Act at the time the Pharmaceutical MACT became effective.

4. A major source of hazardous air pollutant emissions can avoid being subject to MACT requirements by becoming a "synthetic minor" source. In order to become a "synthetic minor" source, a major source is required to comply with federally enforceable restrictions in a permit that limit the facility's emissions of hazardous air pollutants to below 10 tons per year of any individual HAP and below 25 tons per year of total HAPs.

5. EPA published the final rule for Project XL Site-Specific Rulemaking for Merck's Stonewall Plant in the Federal Register on October 8, 1997. 62 FR 52622. The preamble of the final XL rule states:

> *The alternate regulatory system that is established under this site-specific rule and the permit addresses the existing criteria pollutants (and does not include lead). Merck will fully comply with all requirements for the control of HAPs, including the forthcoming Maximum Achievable Control Technology (MACT) standard for the pharmaceutical industry.*

62 FR 52624, III. Summary of Regulatory Requirements for the Merck XL Project.

6. EPA promulgated the final Pharmaceutical MACT in the Federal Register on September 21, 1998. 40 CFR Part 63, Subpart GGG, 63 FR 50280. The final MACT rule established a compliance date for existing major pharmaceutical sources of September 21, 2001; three years following the date of the MACT's promulgation. The MACT included standards for storage tanks (§ 63.1253), process vents (§ 63.1254), including a requirement that certain pharmaceutical processes reduce HAP emissions by 98%, equipment leaks (§ 63.1255), and wastewater (§ 63.1256).

7. In November 1998, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed petitions with the U.S. Court of Appeals for the District of Columbia Circuit for reconsideration of the Pharmaceutical MACT. Issues raised by PhRMA included, among other things, applicability of the rule, the 98% reduction requirement for certain process vents, and recordkeeping requirements. EPA and PhRMA reached a settlement agreement in that action, which called for, among other things, greater flexibility with respect to certain aspects of the rule and additional time for major sources to come into compliance with the MACT. Under the terms of that settlement agreement, the compliance date for the MACT rule for existing pharmaceutical sources was extended from September 21, 2001, to October 21, 2002. EPA published amendments to the Pharmaceutical MACT in accordance with the terms of that settlement agreement on April 10, 2000. 65 FR 19152. EPA promulgated the final revisions to the Pharmaceutical MACT on August 29, 2000. 65 FR 52588.

8. DEQ adopted by reference and became the delegated authority for administration and enforcement of the Pharmaceutical MACT on May 1, 2000. 9 VAC 5-60-100.

9. Merck submitted a synthetic minor permit application for the Stonewall Plant to DEQ on July 2, 2001. Merck's application included a proposed draft permit with synthetic minor permit conditions. DEQ expressed a number of concerns about certain provisions of the proposed draft permit submitted by Merck. These concerns resulted in discussions between Merck and DEQ, with input from EPA Region 3 and EPA's Office of Air Quality and Performance Standards, regarding the proper contents of a synthetic minor hazardous air pollutant permit for a pharmaceutical facility. The concerns that proved most difficult to resolve involved the method to be used by Merck to demonstrate compliance with the synthetic minor emissions limits in the first year after the permit modification and the means to enable a future transition from synthetic minor to major source status under the terms of the permit. As a

result of these prolonged discussions and inability to reach agreement on the terms of the synthetic minor HAP permit, Merck subsequently requested an extension of the Pharmaceutical MACT compliance date for the Stonewall Plant, as discussed in paragraph 11 below.

10. DEQ issued the Stonewall Plant a Title V operating permit effective on October 1, 2001.

11. In a letter to Brad Chewning, Director of DEQ's Valley Regional Office, dated June 21, 2002, Merck requested a one-year extension of the Stonewall Plant's compliance date with the Pharmaceutical MACT to October 21, 2003, pursuant to Section 112(i)(3)(B) of the Clean Air Act. In the June 21 letter, Merck informed DEQ that the Stonewall Plant would "comply" with the MACT rule by becoming a "synthetic minor" source instead of by meeting all of the specific requirements in the MACT, stating:

> *We intend to use the extension to allow us to develop and implement the optimum hazardous air pollutant (HAP) emission control strategy for the Plant's production processes to* ***demonstrate to the satisfaction of the DEQ*** *that we are a synthetic minor source of HAP emissions.*

(Emphasis added.)

DEQ insisted that to be practically enforceable, the first year compliance demonstration must be made using a 12-month rolling total of HAP emissions that would reflect compliance with the emissions limits upon the new Pharmaceutical MACT compliance date of October 21, 2003.

12. Under the Clean Air Act, a state or EPA cannot grant a major source more than three years to come into compliance with a MACT standard. A one-year extension to the three-year compliance deadline may be granted by a state, but only in the event the additional time is necessary for the source to install emissions control essential to comply with the MACT. A state may not grant an extension merely for the purpose of allowing a source that intends to "comply" with the MACT by becoming a synthetic minor source an additional year of major source level emissions following the MACT compliance deadline.

13. Section 112(i)(3) (A) of the Clean Air Act states:

> (A) *After the effective date of any emissions standard, limitation or regulation promulgated under this section and applicable to a source, no person may operate such source in violation of such standard, limitation, or regulation except, in the case of an existing source, the Administrator shall establish a compliance date or dates for each category or subcategory of existing sources, which shall provide for compliance as expeditiously as practicable,* ***but in no event later than 3 years after the effective date of such standard,*** except as provided in subparagraph (B) and paragraphs (4) through (8).

(Emphasis added; deadline extensions under Section 112(i)(4) through (8) are not relevant to this case).

14. Section 112(i)(3)(B) of the Clean Air Act provides that states that have an EPA-approved Title V program such as Virginia, "*may issue a permit that grants an extension permitting an existing source up to 1 additional year to comply with* [MACT] *standards under subsection (d)* ***if such additional period is necessary for the installation of controls***...."

    Id. (Emphasis added).

15. In a letter from Brad Chewning to Merck dated September 20, 2002, DEQ granted Merck the one year extension of the Stonewall Plant's compliance date with the Pharmaceutical MACT until October 21, 2003, contingent upon Merck's compliance with certain specific conditions enumerated in the letter. One of these conditions was that Merck had to demonstrate to DEQ that the Stonewall Plant had complied with the plant's synthetic minor hazardous air pollutant emission limits for the 12-month period between October 21, 2002, and October 20, 2003.

16. DEQ modified the Stonewall Plant's Title V permit to incorporate synthetic minor hazardous air pollutant emission limits effective on October 21, 2002, which was the compliance date the Pharmaceutical MACT. (Condition IV.A.3) The revised Title V permit required that the plant emit no more than 9.9 tons per year of any individual HAP or 24.9 tons per year of total HAPs. Condition IV.A.3.

17. DEQ issued a Notice of Violation (NOV) to Merck on December 11, 2003, for alleged violations of State Air Pollution Control Law and regulations occurring at Merck's Stonewall Plant based upon information reported to and obtained by DEQ. The NOV listed the following alleged violations:

    a. The Stonewall Plant emitted 14.55 tons of methyl chloride, a hazardous air pollutant, from October 21, 2002 through August 2003 in violation of Condition IV.A.3 of its Title V permit, which limits the plant's emissions of any individual HAP to 9.9 tons per year. The emissions of methyl chloride during this period were determined based upon performance stack testing of the air pollution control train associated with the Carbidopa manufacturing process conducted by Merck in October 2003 and the HAP calculation requirements set forth in Condition IV.A.3a. In addition to violating Condition IV.A.3 of the Stonewall Plant's Title V permit, emissions of 14.55 tons of methyl chloride during this period also violated the terms upon which DEQ granted Merck a one year extension of the Pharmaceutical MACT compliance deadline set forth in DEQ's letter to Merck of September 20, 2002, as well as Section 112 of the Clean Air Act.

    b. Merck failed to correctly measure and quantify individual and total emissions of hazardous air pollutants from the Stonewall Plant's wastewater treatment system in violation of Conditions IV.C.10 and IV.B.23 of its Title V permit. Condition IV.C.10 states that individual and total HAP emissions resulting from wastewater treatment "shall be based on TOXCHEM modeling utilizing measured data for influent flow, influent

temperature, and monthly average values for influent HAP concentrations...", and that, "Annual emissions shall be calculated monthly as specified in Condition IV.A.3." Merck violated Condition IV.C.10 by basing its wastewater HAP emission determinations on "measured process data and engineering calculations," rather than upon actual measured data, i.e., monitoring data, from the wastewater influent flow as required by the condition. DEQ issued a Warning Letter to Merck dated August 29, 2003, informing Merck that the Stonewall Plant was not correctly measuring hazardous air pollutants from the plant's wastewater treatment system. Merck disputed DEQ's assertion that Merck's permit requires sampling and analysis of the wastewater influent flow exclusively in order to quantify HAP emissions from the wastewater treatment plant.

c. Merck failed to determine the control efficiency of scrubber SCR-634 associated with the Carbidopa manufacturing process for methyl chloride in violation of Condition IV.D.1 of its Title V permit. Condition IV.D.1 requires Merck to conduct performance tests on several emissions control devices at the Stonewall plant for the purpose of determining the control efficiency of each device, including scrubber SCR-634, within 180 days of October 21, 2002, and to submit those test results to DEQ within 60 days after a test is completed. Merck made a timely submittal of the test results for each of the designated control devices with the exception of scrubber SCR-634, which is part of the air pollution control train associated with the Carbidopa manufacturing process. DEQ issued a warning letter to Merck regarding this violation on August 15, 2003. Subsequently, Merck submitted a performance (stack) test report for SCR-634 to DEQ dated October 2003, approximately five months after the permit's deadline. That performance test, however, failed to determine the control efficiency of SCR-634 for methyl chloride as required by the permit. Merck asserted that its failure to submit a performance test report to DEQ demonstrating compliance with the control efficiency of SCR-634 by the permit's deadline was due to the infeasibility of obtaining a valid characterization of the loading entering SCR-634 due to the presence of two-phase flow that precluded accurate measurement of the vapor flow rate at that location. Merck further asserted that without modifications to the system to address the problem posed by the two-phase flow, determination of an efficiency for SCR-634 alone was infeasible. In addition to violating Condition IV.D.1of the Stonewall Plant's Title V permit, Merck's failure to determine the control efficiency of SCR-634 for methyl chloride also violated the terms upon which DEQ granted Merck a one year extension of the Pharmaceutical MACT compliance deadline set forth in DEQ's letter to Merck of September 20, 2002, as well as Section 112 of the Clean Air Act.

18. In addition to the violations alleged in the December 11, 2003, NOV, the Stonewall Plant emitted approximately 27.12 total tons of hazardous air pollutants from October 21, 2002 through October 2003 in violation of Condition IV.A.3 of its Title V permit, which limits the plant's emissions of total HAPs to 24.9 tons per year. The emissions of total HAPs during this period were determined based upon performance stack testing of the air pollution control train, including SCR-634, associated with the Carbidopa manufacturing process conducted by Merck in October 2003 and the HAP calculation requirements of Conditions IV.A.3a., IV.B.18., and IV.B.19., as well as upon information contained in Merck's "Submission of Monthly HAP Emissions Report" to DEQ dated December 19, 2003. Among the hazardous

air pollutants emitted by the Stonewall Plant were acetonitrile, chlorine, cyanide compounds, 1,2-dimethoxyethane, dimethylformamide, ethylene glycol, hydrazine, hydrochloric acid, methanol, methyl chloride, methyl-tert-butyl ether, toluene, and triethylamine. In addition to violating Condition IV.A.3 of the Stonewall Plant's Title V permit, emissions of approximately 27.12 tons of total HAPs during this period also violated the terms upon which DEQ granted Merck a one year extension of the Pharmaceutical MACT compliance deadline set forth in DEQ's letter to Merck of September 20, 2002, as well as Section 112 of the Clean Air Act.

19. In addition to the violations alleged in the December 11, 2003, NOV, the Stonewall Plant emitted approximately 16.35 tons of methyl chloride, a hazardous air pollutant, from October 21, 2002 through October 2003 in violation of Condition IV.A.3 of its Title V permit, which limits the plant's emissions of any individual HAP to 9.9 tons per year. The emissions of methyl chloride during this period were determined based upon performance stack testing of the air pollution control train, including SCR-634, associated with the Carbidopa manufacturing process conducted by Merck in October 2003 and the HAP calculation requirements of Conditions IV.A.3a., IV.B.18., and IV.B.19., as well as upon information contained in Merck's "Submission of Monthly HAP Emissions Report" to DEQ dated December 19, 2003. In addition to violating Condition IV.A.3 of the Stonewall Plant's Title V permit, emissions of approximately 16.35 tons of methyl chloride during this period also violated the terms upon which DEQ granted Merck a one year extension of the Pharmaceutical MACT compliance deadline set forth in DEQ's letter to Merck of September 20, 2002, as well as Section 112 of the Clean Air Act.

20. Representatives of Merck have met with DEQ officials on numerous occasions following the issuance of the NOV for the purpose of resolving the issues outlined above, including conferences at VRO on January 22, 2004, October 12, 2004, November 1, 2004, November 15, 2004, January 11, 2005, February 25, 2005, April 7, 2005, and June 21, 2005, and on-site meetings at the facility on February 12, 2004, June 22, 2004, November 5, 2004, and November 18, 2004.

21. After October 2003 performance testing of the Carbidopa manufacturing process air pollution control train, including SCR-634, revealed methyl chloride emissions in excess of the individual HAP limit of 9.9 TPY, Merck conducted an investigation of the process and its associated air pollution control system. Merck discovered an erroneous modeling assumption that resulted in the underestimation of actual methyl chloride emissions. To increase the capture and destruction of methyl chloride, Merck found that the quantity and temperature of quencher water had to be controlled and that residual methyl chloride had to be purged from the reactor vessel. Merck has completed the necessary process modifications (Letter from Jett to Chewning dated October 31, 2003, Attachment A) and conducted additional performance testing in November 2003. With the process modifications, this testing demonstrated an average methyl chloride control efficiency of 96.3 percent.

SECTION D: Agreement and Order

Accordingly the State Air Pollution Control Board, by virtue of the authority granted it pursuant to Va. Code §§ 10.1-1186(2), 10.1-1309, and 10.1-1316(C), orders Merck, and Merck voluntarily agrees to comply with the terms and conditions set forth in **Appendix A** and **Appendix B** to this Order and to pay a civil charge of **$500,000.00** in settlement of the violations cited in this Order in accordance with the following:

1. **$200,000.00** of this civil charge shall be paid within 30 days of the effective date of this Order. Payment must indicate that the civil charge is paid pursuant to this Order, and shall include Merck's Federal Identification Number. Payment shall be by check, certified check, money order, or cashier's check payable to **"Treasurer of the Commonwealth of Virginia"** and send to:

   Receipts Control
   Department of Environmental Quality
   P. O. Box 10150
   Richmond, Virginia 23240

2. **$300,000.00** of this civil charge shall be satisfied upon completion of a **Supplemental Environmental Project (SEP)** pursuant to Va. Code § 10.1-1186.2 as described in **Appendix B** of this Order.

If at a later date Merck increases its emissions or potential to emit at the Stonewall Plant such that it becomes a major source of HAPs, Merck waives the compliance period provided by 40 CFR 63.6 (c)(5) (i.e., all relevant MACT requirements would be immediately applicable to the Stonewall Plant).

SECTION E: Administrative Provisions

1. The Board may modify, rewrite, or amend the Order with the consent of Merck, for good cause shown by Merck, or on its own motion after notice to Merck and its opportunity to be heard.

2. This Order addresses and resolves only those violations specifically identified herein. This Order shall not preclude the Board or the Director from taking any action authorized by law, including but not limited to taking any action authorized by law regarding any additional, subsequent, or subsequently discovered violations or taking subsequent action to enforce this Order. This Order shall not preclude appropriate enforcement actions by federal, state, or local regulatory authorities for matters not addressed herein. Merck does not waive any rights it may have to object to enforcement actions by other federal, state, or local authorities arising out of the same or similar facts alleged in this Order.

3. For purposes of this Order and subsequent actions with respect to this Order, Merck admits the jurisdictional allegations but does not admit the factual findings and conclusions of law contained herein.

4. Merck consents to venue in the Circuit Court of the City of Richmond for any civil action taken to enforce the terms of this Order.

5. Merck declares it has received fair and due process under the Administrative Process Act, Va. Code §§ 2.2-4000 *et seq.*, and the Air Pollution Control Law and it waives the right to any hearing or other administrative proceeding authorized or required by law or regulation, and to any judicial review of any issue of fact or law contained herein, except that Merck reserves its right to a hearing or other administrative proceeding authorized or required by law or to judicial review of any issue of fact or law contained in any subsequent amendments to this Order issued by the Board without the consent of Merck. Nothing herein shall be construed as a waiver of the right of Merck to any administrative proceeding for, or to judicial review of, any action taken by the Board to enforce this Order.

6. Failure by Merck to comply with any of the terms of this Order shall constitute a violation of an order of the Board. Nothing herein shall waive the initiation of appropriate enforcement actions or the issuance of additional orders as appropriate by the Board or the Director as a result of such violations. Nothing herein shall affect appropriate enforcement actions by any other federal, state, or local regulatory authority. Merck does not waive any rights it may have to object to enforcement actions by federal, state, or local authorities arising out of the same or similar facts alleged in this Order.

7. If any provision of this Order is found to be unenforceable for any reason, the remainder of the Order shall remain in full force and effect.

8. Merck shall be responsible for failure to comply with any of the terms and conditions of this Order unless compliance is made impossible by earthquake, flood, other acts of God, war, strike, or such other occurrence. Merck shall show that such circumstances were beyond its control and not due to a lack of good faith or diligence on its part. Merck shall notify the DEQ Regional Director in writing when circumstances are anticipated to occur, are occurring, or have occurred that may delay compliance or cause noncompliance with any requirement of the Order. Such notice shall set forth:

   a. the reasons for the delay or noncompliance;

   b. the projected duration of any such delay or noncompliance;

   c. the measures taken and to be taken to prevent or minimize such delay or noncompliance; and

   d. the timetable by which such measures will be implemented and the date full compliance will be achieved.

   Failure to so notify the Regional Director within 24 hours of learning of any condition above, which Merck intends to assert will result in the impossibility of compliance, shall constitute a waiver of any claim to inability to comply with a requirement of this Order.

9. This Order is binding on the parties hereto, their successors in interest, designees and assigns, jointly and severally.

10. This Order shall become effective upon execution by both the Director or his designee and Merck. Notwithstanding the foregoing, Merck agrees to be bound by any compliance date which precedes the effective date of this Order.

11. This Order shall continue in effect until:

a. Merck petitions the Regional Director to terminate this Order after Merck has completed all of the requirements of the Order, including the requirements of Appendices A and B, and the Regional Director has acknowledged in writing to Merck that all of those requirements have been satisfied. The Regional Director's determination that Merck has satisfied all the requirements of this Order is a "case decision" within the meaning of the Virginia Administrative Process Act.

b. The Director or Board may terminate this Order earlier in his or its sole discretion upon 30 days written notice to Merck.

Termination of this Order, or any obligation imposed in this Order, shall not operate to relieve Merck from its obligation to comply with any statute, regulation, permit condition, other order, certificate, certification, standard, or requirement otherwise applicable.

12. By its signature below, Merck voluntarily agrees to the issuance of this Order.

And it is so ORDERED this day of July 8, 2005.

Robert G. Burnley
Department of Environmental Quality

Merck & Co., Inc. voluntarily agrees to the issuance of this Order.

By: _____

Date: 7/8/05

Commonwealth of Virginia
~~City~~/County of Rockingham

The foregoing document was signed and acknowledged before me this 8th day of July, 2005, by Charles F. Vencill (name), who is Plant Manager (title) of Merck & Co., Inc., on behalf of Merck & Co., Inc.

Notary Public

My commission expires: 7/31/06.

APPENDIX A

In addition to the foregoing, the Virginia State Air Pollution Control Board orders Merck to undertake, and Merck agrees to implement, the following terms and conditions of this Appendix:

1. To ensure that control efficiencies for methyl chloride in the Carbidopa process are maintained at the Stonewall facility as demonstrated in performance testing conducted in November 2003, Merck shall provide a certified summary of the process changes that have been installed and implemented to achieve these control efficiencies. This summary shall be provided by September 15, 2005. Merck shall also develop and comply with a plan to operate and maintain these process changes and to monitor parameters related to these process changes on a regular basis. The plan shall be subject to DEQ approval. Merck shall submit this plan to DEQ by October 15, 2005. This plan shall be enforceable under this Order upon the plan's approval by DEQ.

2. Merck shall upgrade the portions of the Stonewall facility's chemical sewer system serving pharmaceutical manufacturing operations from which wastewater streams containing organic HAPs (excluding ethylene glycol) are discharged. This upgrade shall bring these portions of the chemical sewer system into conformance with the applicable emission suppression requirements specified in 40 CFR 63.1256. The chemical sewer system upgrade shall include applicable individual drain systems, open sumps, and basins from the point of discharge up to and including the point where the discharge enters the wastewater treatment plant (WWTP). Merck shall provide a written plan listing each upgrade, including a site schematic showing the upgrade locations. The plan shall be subject to DEQ approval and require that all upgrades to the chemical sewer system specified in the plan be completed and in operation no later than July 15, 2007. Merck shall submit this plan to DEQ by September 15, 2005. This plan shall be enforceable under this Order upon the plan's approval by DEQ.

3. Merck shall install a fixed roof on TA-115 in the WWTP. Merck shall include the upgrade to TA-115 in the upgrade plan, and it shall be subject to the same schedule, as specified in paragraph 2 above.

4. Merck shall complete an engineering assessment to determine the impact of the additional loading of organic HAPs (excluding ethylene glycol) from the projects specified in paragraphs 2 and 3 of this Appendix to the biological treatment unit of the Stonewall facility's WWTP. Merck shall provide DEQ with the results of this evaluation and a determination concerning the need to conduct additional testing in accordance with 40 CFR Part 63, Appendix C within 180 days of the completion of the two projects.

5. By March 15, 2006, Merck shall conduct a performance test on scrubber SCR 1427/1427A for methanol. The performance test shall be conducted according to EPA reference methods and shall be performed to determine control efficiency. One copy of the test results shall be submitted to the DEQ, Valley Regional Office within 60 days after test completion.

6. Merck shall develop an overall site-specific factor for laboratory emissions of methanol at the Stonewall facility. Merck shall submit a method protocol to DEQ for approval by October 15, 2005 and shall provide the factor no later than March 15, 2006. The method employed to develop the site-

specific factor shall be based on the study conducted at the Merck West Point Plant. The Stonewall site-specific factor shall be developed by using the emission factors for individual laboratory operations previously determined by the Merck West Point Plant study, as applicable, but also include emission factors for HPLC and GC operations performed at the Stonewall facility. The Stonewall overall site-specific factor shall be adapted to represent actual laboratory operations at the Stonewall facility.

7. Merck shall sample and analyze at the Stonewall facility's WWTP influent for all organic HAPs (excluding ethylene glycol) for which removal credit in wastewater treatment will be taken, as follows:

   a. Samples shall be collected and analyzed in accordance with DEQ-approved procedures. Merck shall submit sample collection protocols and analytical procedures to DEQ by December 15, 2005. All sample collection protocols and analytical procedures shall be subject to DEQ approval and shall be enforceable under this Order upon their approval by DEQ.

   b. Individual organic HAPs (excluding ethylene glycol) from pharmaceutical manufacturing operations shall be sampled and analyzed at the WWTP influent on a daily basis unless the given organic HAP-containing manufacturing operation did not discharge to the WWTP since the previous sample was collected.

   c. Merck shall maintain records to document when sampling and analysis for specific organic HAPs are required at the WWTP influent in accordance with item 7.b. above.

   d. Any organic HAP (excluding ethylene glycol) used in pharmaceutical manufacturing operations and discharged to the WWTP shall be assumed emitted to the atmosphere if not included in the sampling and analysis procedures.

   e. For instances where one or more daily influent concentration values are determined to be less than the specified limit of quantitation (LOQ), these values shall be treated as zeros in determining monthly average HAP concentrations at the WWTP influent. The monthly average HAP concentrations at the WWTP influent shall be calculated using all available data for the month including the defined zeros.

   f. Pursuant to item 10.b. of this Appendix, Merck shall calculate emissions of organic HAPs (excluding ethylene glycol) from wastewater conveyance systems using the best available information and methods.

8. Merck shall submit to DEQ a report of the following:

   a. Rolling 12-month total HAP emissions (individual and in the aggregate) for each month.

   b. Daily WWTP influent sampling and analysis composite results for each organic HAP (excluding ethylene glycol) or an indication that sampling and analysis was not conducted for the HAP, for each month.

Merck shall submit these reports within 60 days after the end of each calendar month. The first report shall be submitted within 60 days after the end of the first full month after this Order is signed. These monthly reports shall be submitted until this Order is terminated and shall satisfy the quarterly reporting required by Condition IV.E.2 of the Title V permit.

9. Merck shall submit to DEQ updated annual compliance certifications for 2002 and 2003 indicating intermittent compliance with regard to the measurement of HAPs at the WWTP. Merck shall submit these updated certifications by September 15, 2005.

10. Merck shall submit an application to reopen and reissue the facility's Title V permit. The application shall be submitted for the entire facility in accordance with 9 VAC 5-80-90 and shall include the submission of a Compliance Plan incorporating the conditions of this Appendix as new applicable requirements and modifying the recordkeeping provisions of the Title V permit as follows:

    a. In Condition IV.C.8, delete the second sentence stating "Calculations shall include emissions from wastewater conveyance from each process area as specified in Condition IV.B.23."

    b. In Condition IV.C.11, add "wastewater conveyance systems" after "sludge drying and incineration".

    Merck shall submit a complete Title V permit application to DEQ to incorporate these conditions by January 15, 2006.

11. Merck shall submit to DEQ quarterly reports documenting progress in achieving compliance with the conditions of this Appendix. The first status report shall be due within two weeks of the end of the calendar quarter in which the Order becomes effective.

APPENDIX B

Supplemental Environmental Project

In addition to the foregoing, the Virginia State Air Pollution Control Board orders Merck to undertake, and Merck agrees to implement, a Supplemental Environmental Project in accordance with the following terms and conditions:

1. The Supplemental Environmental Project (SEP) to be performed by Merck is a School Bus Retrofit Program to be carried out in Rockingham County, Virginia, or in other suitable locations in Virginia as approved by DEQ. Merck shall supply to DEQ a plan to use $300,000.00 to accomplish any combination of the following concerning in-service diesel-powered school buses in Rockingham County, Virginia:
   a. Retrofitting school buses with pollution control devices and techniques and infrastructure needed to support such retrofits;
   b. Engine replacements that will reduce emissions of particulates or ozone precursors; and/or
   c. Cover the incremental costs of changeover to CNG fuel or ultra low sulfur diesel fuel.

2. Merck's plan must:
   a. Describe how the work or project to be performed is consistent with the requirements of Item #1 above;
   b. Include a general schedule and budget (for at least $300,000.00) for completion of the work along with a requirement of periodic reports to DEQ from Rockingham County on the progress of the work called for in the proposed plan through the completion of the project.
   c. Describe generally the expected environmental benefit for project or work called for under the proposed plan; and
   d. Describe briefly how the work or project described in the proposed plan meets DEQ's SEP policy requirements and guidelines.

3. Merck's obligation for this project shall terminate once DEQ has approved the plan referred to in Item #2 above and Merck has transferred at least $300,000.00 to DEQ for the purpose of funding the project as described in the plan. Merck shall transfer the $300,000.00 to DEQ within 30 days after DEQ has notified Merck in writing of the plan's approval. Payment shall be made according to terms to be established by DEQ.

4. In the event that Merck publicizes the SEP or the results of the SEP, Merck shall state in a prominent manner that the project is part of a settlement for an enforcement action with DEQ.